IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CURRAX PHARMACEUTICALS LLC, Plaintiff, v. MSN LABORATORIES PRIVATE LIMITED and MSN PHARMACEUTICALS INC., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Currax Pharmaceuticals LLC ("Currax"), for its complaint against Defendants MSN Laboratories Private Limited ("MSN Laboratories") and MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") (collectively, "MSN"), hereby alleges as follows:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code.

PARTIES

2. Currax is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10 North Park Place, Suite 201, Morristown, New Jersey 07960.

3. On information and belief, Defendant MSN Laboratories is an Indian corporation, having its principal place of business at MSN House, C-24, Industrial Estate, Sanathnagar, Hyderabad-18, Telangana, India.

4. On information and belief, MSN Pharmaceuticals is a corporation organized under the laws of the State of Delaware, having its principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

5. On information and belief, MSN Pharmaceuticals is a wholly-owned subsidiary of MSN Laboratories.

6. On information and belief, MSN Pharmaceuticals and MSN Laboratories develop, manufacture, and/or distribute generic drugs for sale and use throughout the United States, including in Delaware.

7. On information and belief, MSN Pharmaceuticals and MSN Laboratories are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic drug products. On information and belief, the acts of MSN Pharmaceuticals and MSN Laboratories complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

8. On information and belief, MSN Pharmaceuticals and MSN Laboratories have cooperated and assisted in the preparation and filing of MSN's ANDA No. 214823 ("MSN's ANDA") for MSN's 3 mg and 6 mg doxepin hydrochloride oral tablets ("MSN's Products"), and will be involved in the manufacture, importation, marketing, and sale of the drug that is the subject of MSN's ANDA if it is approved.

JURISDICTION AND VENUE

9. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

11. This Court has personal jurisdiction over MSN Pharmaceuticals because, on information and belief, MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware.

12. This Court has personal jurisdiction over MSN Laboratories because, *inter alia*, MSN Laboratories, itself and/or through its wholly-owned subsidiaries, has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, MSN Laboratories directly or indirectly is in the business of developing, manufacturing, marketing, importing, offering to sell and selling pharmaceutical drug products, including generic drug products, throughout the United States, including in Delaware. Upon information and belief, MSN Laboratories derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. Delaware would be a destination of MSN's Products upon approval and marketing of the ANDA involved in this action. MSN Laboratories's filing of its ANDA constitutes a formal act that reliably indicates its plans to engage in marketing of the accused infringing ANDA products in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

13. Alternatively, assuming that the above facts do not establish personal jurisdiction over MSN Laboratories, this Court may exercise jurisdiction pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Currax's claims arise under federal law; (b) MSN Laboratories is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) MSN Laboratories has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed

throughout the United States, such that this Court's exercise of jurisdiction over MSN Laboratories satisfies due process.

14. This Court also has personal jurisdiction over MSN Laboratories because it has affirmatively availed itself of the jurisdiction of this Court through the assertion of counterclaims in suits brought in this District and/or by being sued in this District without challenging personal jurisdiction. *See, e.g., Vanda Pharmaceuticals, Inc. v. MSN Pharmaceuticals Inc. et al.,* Civil Action No. 19-926 (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al., v. MSN Laboratories Private Ltd. et al.,* Civil Action No. 18-1785 (D. Del.); *Millennium Pharmaceuticals, Inc. v. MSN Laboratories Private Ltd. et al.*, Civil Action No. 16-1255 (D. Del.).

THE SILENOR® NDA

15. Currax holds approved New Drug Application ("NDA") No. 22-036 for SILENOR® (doxepin hydrochloride) tablets for oral administration (3 mg and 6 mg dosage strengths), which contain the active ingredient doxepin. SILENOR® tablets were approved by the United States Food and Drug Administration ("FDA") on March 17, 2010. SILENOR® tablets are indicated for the treatment of insomnia characterized by difficulties with sleep maintenance. SILENOR® tablets are sold in the United States by Currax.

THE PATENTS-IN-SUIT

16. Currax is the owner of U.S. Patent No. 7,915,307 ("the '307 patent"). The '307 patent was duly and legally issued on March 29, 2011. A true copy of the '307 patent is attached as Exhibit A.

17. Currax is the owner of U.S. Patent No. 9,532,971 ("the '971 patent"). The '971 patent was duly and legally issued on January 3, 2017. A true copy of the '971 patent is attached as Exhibit B.

18. Currax is the owner of U.S. Patent No. 9,572,814 ("the '814 patent"). The '814 patent was duly and legally issued on February 21, 2017. A true copy of the '814 patent is attached as Exhibit C.

19. Currax is the owner of U.S. Patent No. 9,907,780 ("the '780 patent"). The '780 patent was duly and legally issued on March 6, 2018. A true copy of the '780 patent is attached as Exhibit D.

20. Currax is the owner of U.S. Patent No. 10,548,871 ("the '871 patent"). The '871 patent was duly and legally issued on February 4, 2020. A true copy of the '871 patent is attached as Exhibit E.

21. Currax is the owner of U.S. Patent No. 10,653,660 ("the '660 patent"). The '660 patent was duly and legally issued on May 19, 2020. A true copy of the '660 patent is attached as Exhibit F.

22. The '307, '971, '814, '780, '871, and '660 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Currax's SILENOR® tablets.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

23. On information and belief, MSN submitted its ANDA to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, and sale of MSN's Products as generic versions of Currax's SILENOR® tablets.

24. By a letter dated June 29, 2020 ("Notice Letter"), MSN advised Currax that it had submitted its ANDA to the FDA seeking approval to engage in the manufacture, use, or sale of MSN's Products before the expiration of the '307, '971, '814, '780, and '871 patents. On information and belief, MSN is also seeking approval to engage in the manufacture, use, or sale of MSN's Products before the expiration of the '660 patent.

25. On information and belief, when MSN filed its ANDA, it was aware of the '307, '971, '814, '780, '871, and '660 patents and it was aware that the filing of its ANDA was an act of infringement of those patents.

26. By submitting its ANDA, MSN has necessarily represented to the FDA that, upon approval, MSN's Products will have the same active ingredient, method of administration, dosage form, and strength as Currax's SILENOR® tablets, and will be bioequivalent to Currax's SILENOR® tablets.

27. On information and belief, MSN's ANDA seeks FDA approval of MSN's Products to be indicated for the treatment of insomnia characterized by difficulties with sleep maintenance.

28. On information and belief, MSN has taken and continues to take active steps towards the manufacture, use, offer for sale, sale, and/or importation of MSN's Products, including seeking approval of those products under MSN's ANDA.

29. Currax will be substantially and irreparably harmed by the infringing activities described in the Counts below unless those activities are precluded by this Court. Currax has no adequate remedy at law.

COUNT I

INFRINGEMENT OF THE '307 PATENT

30. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

31. MSN submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of MSN's Products throughout the United States, including in this judicial district, prior to expiration of the '307 patent. By submitting its ANDA, MSN committed an act of infringement of the '307 patent under 35 U.S.C. § 271(e)(2)(A).

32. On information and belief, MSN's manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's Products prior to the expiration of the '307 patent will infringe the '307 patent under 35 U.S.C. § 271(b). MSN will infringe one or more of the claims of the '307 patent.

33. The '307 patent claims, *inter alia*, methods for providing sleep therapy wherein doxepin is administered at least three hours after consuming a meal. For example, claim 1 of the '307 patent claims the following:

> A method for providing sleep therapy comprising administering a 3 mg or a 6 mg dose of doxepin to an individual at least three hours after consuming a meal, thereby providing a faster onset of action and reducing next day residual effects.

34. On information and belief, MSN will knowingly provide MSN's Products with instructions for administering those products in a manner that directly infringes one or more claims of the '307 patent. On information and belief, if MSN's ANDA is approved, physicians and/or patients following said instructions will directly infringe the '307 patent. On information and belief, if MSN's ANDA is approved, MSN will actively encourage, recommend, or promote

this infringement with knowledge of the '307 patent and knowledge that its acts will induce infringement of the '307 patent.

COUNT II

INFRINGEMENT OF THE '971 PATENT

35. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

36. MSN submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of MSN's Products throughout the United States, including in this judicial district, prior to expiration of the '971 patent. By submitting its ANDA, MSN committed an act of infringement of the '971 patent under 35 U.S.C. § 271(e)(2)(A).

37. The '971 patent claims, *inter alia*, pharmaceutical compositions comprising amounts of doxepin (*e.g.*, "from about 0.5 to about 7 mg") and other claimed ingredients. For example, claim 1 of the '971 patent claims:

> A pharmaceutical composition comprising from about 0.5 to about 7 mg of doxepin, or a pharmaceutically acceptable salt thereof, and from about 92% to about 99.8% w/w silicified microcrystalline cellulose, the composition having one or more of the characteristics selected from the group consisting of: a hardness value of at least 2 Kp, a friability value of 1% or less, a disintegration time of about 1 minute as per USP protocols, at least an 80% release of doxepin within 15 minutes using compendial method for measuring dissolution of doxepin, at least an 85 percent release of doxepin within 30 minutes using U.S. Pharmacopeia (USP) Apparatus I at 100 rpm (or Apparatus II at 50 rpm) in 0.1 N HCl or Simulated Gastric Fluid USP without enzymes, at least an 85 percent release of doxepin within 30 minutes using U.S. Pharmacopeia (USP) Apparatus I at 100 rpm (or Apparatus II at 50 rpm) in a pH 4.5 buffer, and at least an 85 percent release of doxepin within 30 minutes using U.S. Pharmacopeia (USP) Apparatus I at 100 rpm (or Apparatus II at 50 rpm) in a pH 6.8 buffer or Simulated Intestinal Fluid USP without enzymes; and

> wherein the pharmaceutical composition has dissolution and bioavailablity characteristics such that after administration to a 70 kg human, the composition provides a plasma concentration of at least 0.05 ng/mL doxepin within a time frame of not more than about 90 minutes.

38. On information and belief, MSN's Products consist of pharmaceutical compositions patented in the '971 patent.

39. On information and belief, MSN's manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's Products prior to the expiration of the '971 patent will infringe the '971 patent under 35 U.S.C. § 271(a). MSN will infringe one or more of the claims of the '971 patent, either literally or under the doctrine of equivalents.

40. On information and belief, MSN knows or should know that its manufacture, use, offer for sale, sale, and/or importation of MSN's Products prior to patent expiration will infringe one or more claims of the '971 patent.

COUNT III

INFRINGEMENT OF THE '814 PATENT

41. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

42. MSN submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of MSN's Products throughout the United States, including in this judicial district, prior to expiration of the '814 patent. By submitting its ANDA, MSN committed an act of infringement of the '814 patent under 35 U.S.C. § 271(e)(2)(A).

43. On information and belief, MSN's manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's Products prior to the expiration of the '814

patent will infringe the ’814 patent under 35 U.S.C. § 271(b). MSN will infringe one or more of the claims of the ’814 patent.

44. The ’814 patent claims, *inter alia*, methods for treating insomnia wherein doxepin is administered at least three hours after consuming a meal. For example, claim 1 of the ’814 patent claims the following:

> A method of treating insomnia, the method comprising administering between about 0.5 mg and about 7 mg doxepin to a patient in need thereof, wherein the doxepin is administered before bedtime and at least three hours after consuming a meal, thereby providing a faster onset of action and reducing next day residual effects.

45. On information and belief, MSN will knowingly provide MSN’s Products with instructions for administering those products in a manner that directly infringes one or more claims of the ’814 patent. On information and belief, if MSN’s ANDA is approved, physicians and/or patients following said instructions will directly infringe the ’814 patent. On information and belief, if MSN’s ANDA is approved, MSN will actively encourage, recommend, or promote this infringement with knowledge of the ’814 patent and knowledge that its acts will induce infringement of the ’814 patent.

COUNT IV

INFRINGEMENT OF THE ’780 PATENT

46. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

47. MSN submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of MSN’s Products throughout the United States, including in this judicial district, prior to expiration of the ’780 patent. By

submitting its ANDA, MSN committed an act of infringement of the '780 patent under 35 U.S.C. § 271(e)(2)(A).

48. The '780 patent claims, *inter alia*, pharmaceutical compositions comprising amounts of doxepin (*e.g.*, "from about 0.5 to about 7 mg") and other claimed ingredients. For example, claim 1 of the '780 patent claims the following:

> A pharmaceutical composition comprising about 0.5 to about 7 mg of doxepin, or a pharmaceutically acceptable salt thereof, and about 92% to about 99.8% w/w silicified microcrystalline cellulose.

49. On information and belief, MSN's Products consist of pharmaceutical compositions patented in the '780 patent.

50. On information and belief, MSN's manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's Products prior to the expiration of the '780 patent will infringe the '780 patent under 35 U.S.C. § 271(a). MSN will infringe one or more of the claims of the '780 patent, either literally or under the doctrine of equivalents.

51. On information and belief, MSN knows or should know that its manufacture, use, offer for sale, sale, and/or importation of MSN's Products prior to patent expiration will infringe one or more claims of the '780 patent.

COUNT V

INFRINGEMENT OF THE '871 PATENT

52. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

53. MSN submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of MSN's Products throughout the United States, including in this judicial district, prior to expiration of the '871 patent. By

submitting its ANDA, MSN committed an act of infringement of the '871 patent under 35 U.S.C. § 271(e)(2)(A).

54. On information and belief, MSN's manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's Products prior to the expiration of the '871 patent will infringe the '871 patent under 35 U.S.C. § 271(b). MSN will infringe one or more of the claims of the '871 patent, either literally or under the doctrine of equivalents.

55. The '871 patent claims, *inter alia*, methods wherein doxepin or a pharmaceutically acceptable salt thereof is administered to treat insomnia. For example, claim 1 of the '871 patent claims the following:

> A method of treating insomnia, the method comprising administering to a patient in need thereof a pharmaceutical composition comprising about 0.5 to about 7 mg of doxepin, or a pharmaceutically acceptable salt thereof, and about 92% to about 99.8% w/w silicified microcrystalline cellulose.

56. On information and belief, MSN will knowingly provide MSN's Products with instructions for administering those products in a manner that directly infringes one or more claims of the '871 patent. On information and belief, if MSN's ANDA is approved, physicians and/or patients following said instructions will directly infringe the '871 patent. On information and belief, if MSN's ANDA is approved, MSN will actively encourage, recommend, or promote this infringement with knowledge of the '871 patent and knowledge that its acts will induce infringement of the '871 patent.

COUNT VI

INFRINGEMENT OF THE '660 PATENT

57. Currax incorporates each of the preceding paragraphs as if fully set forth herein.

58. MSN submitted its ANDA to the FDA to obtain approval to engage in the manufacture, use, offer for sale, sale, and/or importation of MSN's Products throughout the United States, including in this judicial district, prior to expiration of the '660 patent. By submitting its ANDA, MSN committed an act of infringement of the '660 patent under 35 U.S.C. § 271(e)(2)(A).

59. On information and belief, MSN's manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's Products prior to the expiration of the '660 patent will infringe the '660 patent under 35 U.S.C. § 271(b). MSN will infringe one or more of the claims of the '660 patent.

60. The '660 patent claims, *inter alia*, methods for treating insomnia wherein doxepin is administered at least three hours after consuming a meal. For example, claim 1 of the '660 patent claims the following:

> A method of treating insomnia in a patient in need thereof, the method comprising: administering between about 0.5 mg and about 7 mg doxepin to the patient, wherein the doxepin is administered at least 3 hours after consuming a meal to provide faster onset of action and minimize potential for next day sedation effects.

61. On information and belief, MSN will knowingly provide MSN's Products with instructions for administering those products in a manner that directly infringes one or more claims of the '660 patent. On information and belief, if MSN's ANDA is approved, physicians and/or patients following said instructions will directly infringe the '660 patent. On information and belief, if MSN's ANDA is approved, MSN will actively encourage, recommend, or promote this infringement with knowledge of the '660 patent and knowledge that its acts will induce infringement of the '660 patent.

PRAYER FOR RELIEF

WHEREFORE, Currax respectfully requests the following relief:

A. A judgment that MSN has infringed one or more claims of the ’307, ’971, ’814, ’780, ’871, and/or ’660 patents by submitting its ANDA seeking FDA approval for the manufacture, use, offer for sale, sale, and/or importation of MSN’s Products under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that MSN’s manufacture, use, offer for sale, sale, and/or importation into the United States of MSN’s Products will infringe one or more claims of the ’307, ’971, ’814, ’780, ’871, and/or ’660 patents under 35 U.S.C. §§ 271(a) and/or (b);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining MSN, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the manufacture, use, offer for sale, sale, and/or importation into the United States of MSN’s Products prior to the expiration dates of the ’307, ’971, ’814, ’780, ’871, and/or ’660 patents;

D. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of MSN’s ANDA shall be a date that is not earlier than the expiration dates of the ’307, ’971, ’814, ’780, ’871, and/or ’660 patents;

E. A declaration that this case is “exceptional” under 35 U.S.C. § 285 and an award of attorney fees;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: August 13, 2020

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